

## **REMARKS**

Claims 1-35 and 39-83 are pending in the current application. In response to the Restriction Requirement issued on October 2, 2002, Applicants provisionally elected to prosecute claims 1-16, 22-24, 32-32, 36-38, 43, 80, 82 and 83. In the Office Action issued on June 26, 2003, the Examiner further withdrew claims 22-24, 80, 82 and 83 as being drawn to the non-elected invention. In response, Applicants submitted an Amendment on October 27, 2003, amending claims 1-4, 7, 12, 13 and 15. By way of the Amendment submitted by Applicants on January 14, 2005, claims 36-38 were cancelled.

By way of the present Amendment, Applicants have amended claims 1-4 and 43. No new matter has been added by way of these amendments.

### **Claim Objection**

Applicants note that the Examiner has objected to claim 13 as depending from a rejected claim, but that claim 13 would be allowable if rewritten in independent form.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejected claims 1-11, 32 and 43 under 35 U.S.C. § 112, second paragraph, as allegedly lacking antecedent basis for the phrase, “the biological activity of FGF23.” Applicants respectfully disagree with the Examiner’s interpretation of the claims in view of the specification, and contend that the claims are imbued with sufficient antecedent basis. This is because Applicants have clearly set forth, at lines 27-32 on page 20 of the present application, that the biological activity of FGF23 is the “ability of a molecule to bind an FGF receptor and alter phosphate transport.”

The Examiner questions, for example, on page 4 of the Office Action, whether an FGF23 mutant that does not have FGF23 biological activity is encompassed by the claims. Applicants respectfully point out that the claims rejected by the Examiner *include* the limitation that the polypeptide encoded by the claimed polynucleotide “has the biological activity of FGF23.” Therefore, a polypeptide devoid of FGF23 biological activity would clearly not be encompassed by the claims.

Nonetheless, in a good faith attempt to advance prosecution, and taking the Examiner up on the invitation to include a biological activity of FGF23, Applicants have

amended independent claims 1-4 and 43 to recite, “...wherein the polypeptide encoded by said nucleic acid has the ability to bind an FGF receptor and alter phosphate transport.” Applicants submit that this amendment does not render the claims indefinite, and that the amendment is fully supported at lines 27-32 on page 20 of the present specification, which sets forth that the biological activity of FGF23 is the “ability of a molecule to bind an FGF receptor and alter phosphate transport.”

The ability to alter phosphate transport is fully supported in the as-filed specification, where Applicants provide examples of the ability of wild type FGF23 polypeptide to increase clearance of phosphate from an organism. Further, Applicants provide examples of several mutants of FGF23 and describe the ability of such mutants to increase the rate or degree of clearance of phosphate from an organism to a greater degree than that observed with wild type FGF23 (see, e.g., lines 18-31 on page 24 of the specification). Therefore, “biological activity of FGF23” properly encompasses FGF23 molecules that alter phosphate transport.

The Examiner defines this indefiniteness rejection as one based on a “lack of antecedent basis.” Applicants respectfully remind the Examiner that, according to MPEP § 2173.05(e):

If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. *Ex parte Porter*, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) (“controlled stream of fluid” provided reasonable antecedent basis for “the controlled fluid”). Inherent components of elements recited have antecedent basis in the recitation of the components themselves.

The ability to “alter” phosphate transport *inherently* makes reference to an *un-altered* state. Therefore, the ability of an FGF23 molecule of the invention to “alter” phosphate transport is necessarily considered in reference to the state of phosphate transport in the absence of such molecule. For example, contacting a subject with exogenous wild type FGF23 would have a measurable effect on phosphate transport in the subject, regardless of whether the subject possessed any inherent wild type FGF23. That is, the *difference* in the rate or degree of phosphate transport is measured from the point before contacting a subject with wild type exogenous FGF23 to the point after contacting the subject with exogenous wild type FGF23. Applicants respectfully submit that the skilled artisan would understand that the biological activity of wild type FGF23, or of any FGF23 encompassed by the presently-claimed invention,

is evaluated in comparison to the state of phosphate transport in the absence of any such FGF23 molecule.

Accordingly, Applicants respectfully submit that amended claims 1-4 and 43, and dependent claims 5-11 and 32, are not indefinite, and request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

#### Rejections Under 35 U.S.C. § 102(e)

Claims 3-4, 12, 14-16 and 33 were rejected under 35 U.S.C. § 102(e) as being anticipated by either US 2002/0082205A1 (Itoh, et al.) or US 2002/0102604A1 (Milne Edwards et al.). Applicants respectfully traverse the rejection for the following reasons, which illustrate that neither Itoh nor Milne Edwards anticipates the presently claimed invention under 35 U.S.C. § 102(e).

35 U.S.C. § 102(e) provides that:

A person shall be entitled to a patent unless –

(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language [.] (Emphasis added)

According to 35 U.S.C. § 102(e)(1), the Itoh and Milne Edwards patent applications each must have been filed before the invention, by Applicants, of claims 3-4, 12, 14-16 and 33, in order to anticipate these claims under Section 102(e). Applicants submit that neither reference meets this burden. Furthermore, 35 U.S.C. § 102(e)(2) does not apply under the present circumstances, as neither the Itoh reference nor the Milne Edwards reference are a “patent.”

Applicants direct the Examiner’s attention to the Declaration under 37 C.F.R. § 1.131 submitted on January 14, 2005, in which Applicants establish a date of invention for the instant claims as a date before December 8, 1999, which is earliest priority date for the Itoh and Milne Edwards references cited by the Examiner. This Declaration properly establishes that Applicants are entitled to the presently-claimed polynucleotides. Applicants direct the Examiner’s attention also to the arguments related to the Declaration and the establishment of the

date of invention, set forth on page 18 of the Amendment filed on January 14, 2005, which is incorporated herein by reference in its entirety.

The Examiner contends that the Declaration is not effective, and that under MPEP § 715.05, Applicants' remedy in the present situation must be by an interference under 37 C.F.R. § 41, et seq. Applicants do understand that according to MPEP § 715, an affidavit or declaration under 37 C.F.R. § 1.131 is not appropriate in certain situations, including, "(B) Where the reference U.S. patent or U.S. patent application publication claims the same patentable invention. See MPEP § 715.05 for a discussion of "same patentable invention" and MPEP § 2300" (emphasis added). However, upon review of MPEP § 715.05, Applicants find that MPEP § 715.05 provides that:

When the reference in question is a non-commonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 § CFR 41.202 instead of 37 CFR § 1.131. (emphasis added).

Applicants respectfully point out that the phrase "It's publication date" refers to the publication date of the reference relied upon by the Examiner. That is, the publication date of the reference relied upon by the Examiner must be earlier than the presentation of matching claims in the application under examination.

Accordingly, MPEP § 715.05 requires that the Itoh and Milne Edwards references relied upon by the Examiner would have to have been published less than one year prior to the presentation of Applicants' claims. However, Applicants' claims were presented for examination at the time of filing of the present application, on July 10, 2001, prior to the publication of the Itoh and Milne Edwards references. The Itoh reference was not published until June 27, 2002, and the Milne Edwards reference was not published until August 1, 2002. Therefore, Applicants' January 14, 2005, Declaration under 37 C.F.R. § 1.131 is indeed proper, and the Declaration properly establishes that Applicants are entitled to the presently-claimed polynucleotides.

As set forth above, the Examiner suggests that the solution regarding the rejection under 35 U.S.C. § 102(e) is to file a request for Interference under 37 C.F.R. § 41, et seq. However, a review of the publicly available file histories of the Itoh and Milne Edwards patent

applications reveals that neither of these applications presently includes claims to a nucleic acid encoding FGF23. In fact, a restriction requirement was issued in both applications whereby claims to FGF23 nucleic acids were deemed to be patentably distinct from the claims currently pending in both the Itoh and Milne Edwards applications. Thus, by definition, the Itoh and Milne Edwards applications, as presently pending before the USPTO, do not claim interfering subject matter with the claims in Applicants' application. Clarification by the Examiner on the issue of the rejection under 35 U.S.C. § 102(e) is respectfully requested if the Examiner, upon review of the arguments set forth herein, wishes to maintain the rejection.

Alternatively, Applicants respectfully request the Examiner's reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e).

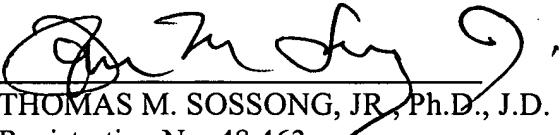
Summary

Applicants respectfully submit that the claims are fully supported in the specification as filed, and that no new matter has been added by way of the present Amendment.

Favorable examination and allowance of the claims is hereby requested.

Respectfully submitted,

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